DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993-0002

CYBER LETTER

July 15, 2013

Richard Cervelli
Robert Silverstein
Origin BioMed Inc.
5162 Duke Street, Suite 500
Halifax, Nova Scotia, B3J 1N7
Canada
info@originbiomed.com

Dear Messrs. Cervelli and Silverstein:

This is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed the information on your firm's website www.originbiomed.com, Facebook Account (www.facebook.com/Neuragen), Twitter Account (www.twitter.com/Neuragen), and product labels for your marketed products which includes, but may not be limited to, "Neuragen PN" and "Neuragen Cream." Based on our review of the labeling claims, your products "Neuragen PN" and "Neuragen Cream" are misbranded under sections 503(b) and 301 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 353(b) and 331].

Examples of labeling claims observed establishing intended use for "Neuragen PN" and "Neuragen Cream" include, but may not be limited to, the following:

Neuragen PN

- **On Your Website**:
  - "[T]opical treatment for severe, disabling nerve pain . . .."
  - "Neuragen PN . . . is effective in relieving pain in a variety of nerve related conditions such as diabetic neuropathy, shingles, and fibromyalgia."

Neuragen Cream

- **On Your Website**:
  - "Easy to use for localized nerve pain . . ."

Neuragen PN and Neuragen Cream

- **On Your Website**:
  - "Neuragen is proven to be effective in relieving nerve pain caused by a variety of conditions."
  - "By recommending safe and clinically proven Neuragen, you will be providing your patients with a non-prescription, effective relief for acute and chronic nerve pain . . .."
  - "Recommended for: Patients with nerve pain (including diabetic nerve pain)."
  - "Neuragen is clinically shown to reduce neuropathic (nerve) pains quickly . . .."
  - "Diabetic Nerve Pain? . . . Chronic Nerve Pain? . . . Neuragen – Relief NOW! . . . Nerve Pain Relief . . ."
  - "Neuragen works by reducing the spontaneous firing of damaged peripheral nerves."
  - "Instead of masking pain symptoms . . . Neuragen goes deep to where the pain originates."
  - "Neuragen is recommended for all types of neuropathy."
  - "Neuragen and Neuragen Cream are both topical treatments for diabetic peripheral neuropathy."
  - "Neuragen PN and Neuragen Cream are topical products that work directly at the site of nerve pain . . .."
  - "Neuragen can be used daily indefinitely to control painful neuropathy."
  - "Neuragen is the first non-prescription topical homeopathic treatment for rapid relief of diabetic and post-shingles nerve pain."
  - "Neuragen is . . . for so many patients with diabetes who suffer from painful diabetic nerve damage."
- **Testimonial on Your Website**:
  - "I just bought and used Neuragen . . . I have diabetes and neuropathy in my feet . . . Neuragen worked within 30 minutes."
- **On Your Facebook Account – Wall Postings by Neuragen**:

- August 16, 2012 – "A testimonial from a neuropathy patient: 'I just discovered Neuragen. It is nothing short of a miracle. I have suffered from peripheral neuropathy for years. I've taken drugs that put me in a stupor. Nothing has put more than a tiny dent in my pain. Within minutes of putting a few drops of Neuragen on my heel, the pain was gone. Completely gone! At first I thought that it was a placebo effect, but it worked again the next day. After a few days I'm finding I only need it every other day. Not one day has my pain ever been as strong as it was before I applied Neuragen the first time.'"

- September 30, 2011 – "If the pain you experience is stabbing, shooting, tingling or burning, you have nerve pain. Neuragen cream will provide you with fast relief."

- **On Your Facebook Account – Wall Postings by Others**:
  - December 2, 2012 – "[M]y wife has been using Neuragen since I discovered the product . . . and for her it gives relief from almost constant neuropathic pain."

  - June 10, 2012 – "If you have pain, you really need to try this stuff . . . . Because of my chemo treatments, I got neuropathy, that is why I use it."

  - May 1, 2012 – "I just bought the topical solution of this today. I have nerve pain . . . This gave almost immediate relief."

- **On YouTube – accessed from your Facebook account posting**:
  - "[T]ry . . . Neuragen . . . relief from nerve pain" http://www.youtube.com/watch?v=cYTMrXiOPQI

  - "[T]ry . . . Neuragen . . . relief from nerve pain" http://www.youtube.com/watch?v=0jRDuLuUUwQ

- **On Your Twitter Account**:
  - Twitter Account Heading – "Clinically proven, topical, homeopathic analgesic solution for the rapid, temporary relief of the nerve pain in the hands and feet."

These claims are supplemented by the common name shared by your products, "neuragen." The name "neuragen" itself implies an association with "nerve pain," because of its resemblance to the word "neuralgia" (nerve pain caused by nerve irritation or damage).

Based on the above-mentioned claims for your products "Neuragen PN" and "Neuragen Cream," they are drugs as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the

body. You promote your products to treat or manage neuropathic pain caused by various underlying conditions, especially in people with neuropathic pain associated with diabetic neuropathy. Section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)] identifies criteria for determining the prescription status of a product. Your products "Neuragen PN" and "Neuragen Cream" are prescription drugs within the meaning of section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)], because they are intended to treat diseases that require diagnosis and treatment by a physician or are intended to provide treatment for symptoms usually caused by an underlying disease process that requires diagnosis and treatment by a physician. Because they are subject to § 503(b)(1) of the FD&C Act, "Neuragen PN" and "Neuragen Cream" are misbranded under section 503(b)(4) of the FD&C Act [21 U.S.C. § 353(b)(4)] in that their labels fail to bear the symbol "Rx only."[1] The introduction or delivery for introduction into interstate commerce of misbranded drugs violates section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

We recognize that "Neuragen PN" and "Neuragen Cream" are represented as being homeopathic drugs with active ingredients measured in homeopathic strengths. The definition of "drug" in section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval. We acknowledge that many homeopathic drugs are manufactured and distributed without FDA approval under enforcement policies set out in the Agency's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). As its title suggests, the CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed; thus, in order to fall under the enforcement policies set forth in the CPG, a homeopathic product must meet the conditions set forth in the CPG. One of those conditions is compliance with section 503(b) of the FD&C Act. Under the CPG, only homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed over-the-counter (OTC). Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

[1] The Agency's guidance, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)," states that, in accordance with § 503(b)(1) of the FD&C Act, homeopathic drug products offered for conditions that require diagnosis or treatment by a licensed practitioner must bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription." This guidance was issued by the agency in 1988. In 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA); section 126 of FDAMA amended § 503(b)(4) of the FD&C Act to require that the label of a prescription drug must bear, at a minimum, the symbol "Rx only."

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to:

U.S. Food and Drug Administration
CDER/OC/OUDLC
10903 New Hampshire Avenue, WO51
Silver Spring, MD 20993-0002
OUDLCMail@fda.hhs.gov

Sincerely,

/s/

Howard Sklamberg
Director
Office of Compliance
Center for Drug Evaluation and Research